

In re application of
Wahl and O'Gorman
Application No.: 10/086,542

Atty. Dkt. No. SALK1790-6 (088802-3457)

REMARKS

Courtesies extended to Applicants' representative in the telephone discussion held March 16, 2005 are acknowledged with appreciation.

In accordance with the present invention, there are provided transgenic, non-human mammals containing at least one FLP recombination target site in their genomic DNA. FLP recombinase target site-containing transgenic mammals may further contain a nucleotide sequence encoding, and capable of being expressed therein, an FLP recombinase to thereby effect FLP-mediated recombination. By incorporating an FLP recombination target site, the chromosomal site of transgene integration is controlled, providing a significant advantage over traditional transgenic methodologies that rely on random integration of the transgene. In addition, the level, temporal characteristics, or tissue distribution of transgene expression may be further regulated. For example, specific promoter systems may be used to control FLP recombinase expression, and thus, to control FLP-mediated recombination of a transgene.

By the present communication, claims 1 and 9 have been amended to define Applicants' invention with greater particularity. These amendments do not add any new matter as they are fully supported throughout the specification and claims as originally filed.

It is respectfully submitted that entry of the amendments submitted herewith is proper because these amendments place the present application in condition for allowance or at a minimum, in better condition for appeal. It is further submitted that these amendments merely implement the alternative claim language discussed during the telephone interview with the Examiner. Accordingly, entry of the amendments submitted herewith is respectfully requested.

Upon entry of the amendments to the claims set forth above, claims 1-10 and 12-19 remain pending in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is

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presented, beginning on page 2 of this paper under "Listing of Claims" with an appropriate defined status identifier.

L. Sequence Compliance

The assertion in the Office Action that the application allegedly fails to comply with the requirements of 37 CFR 1.821-1.825 has been rendered moot by the amendments to claim 1 submitted herewith. Consistent with the telephone discussion with the Examiner, claim 1 has been amended to make reference to the 13-base pair repeats of SEQ ID NO:3, which, in view of the discussion at paragraph 28 of Applicants' specification, is submitted to clearly indicate the two 13-base pair segments which abut each end of an 8-base pair spacer segment. Accordingly, there is no need for submission of a replacement Sequence Listing.

II. 35 U.S.C. §112, 1st Paragraph (Enablement)

The rejection of claims 1-10 and 12-19 under 35 U.S.C. § 112, first paragraph for alleged lack of enablement is respectfully traversed for at least the reasons already of record.

Specifically, Applicants respectfully disagree with the Examiner's assertion that "the specification does not reasonably provide enablement for any FLP recombination target site comprising 5'-GAAGTTCCATTCTTC-3', or 5'-GTATAGGAACTTC-3'" (Office Action, page 3; emphasis in original). It is respectfully submitted that the specification provides both structural and functional information which describes an FLP recombination target site contemplated for use herein, thereby fully enabling the claims.

However, consistent with the telephone discussion with the Examiner, and in order to reduce the issues and expedite prosecution, this rejection has been rendered moot by the amendments to claim 1 submitted herewith. As currently amended, claim 1 recites the "FLP recombination target site comprises the 13 base-pair repeats of SEQ ID NO:3, separated by an 8 base-pair spacer." This amendment is also consistent with that which the Examiner has

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acknowledged to have been enabled (see Office Action, page 3). Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

III. 35 U.S.C. §112, 1st Paragraph (Written Description)

The rejection of claims 1-10 and 12-19 under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement is respectfully traversed.

Applicants respectfully disagree with the Examiner's assertion that "the FLP recombinase target sites encompassed by the claims lack a written description" (Office Action, page 5). Contrary to the Examiner's assertion, the specification provides ample description of FLP recombinase target sites with respect to both structure and function. For example, an exemplary sequence of an FLP recombinase target site is presented in SEQ ID NO:3. Further description of FLP recombinase target sites is provided at, for example, paragraph 28. The function of FLP recombinase target sites in FLP-mediated recombination is depicted in Figures 1A and 1B and is described in the specification at, for example, paragraph 29. Therefore, it is respectfully submitted that the written description requirement has been fully satisfied.

However, consistent with the telephone discussion with the Examiner, and in order to reduce the issues and expedite prosecution, this rejection has been rendered moot by the amendments to claim 1 submitted herewith. As currently amended, claim 1 recites the "FLP recombination target site comprises the 13 base-pair repeats of SEQ ID NO:3, separated by an 8 base-pair spacer." Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

IV. 35 U.S.C. §112, 2nd Paragraph

The rejection of claim 9 under 35 U.S.C. § 112, second paragraph as being allegedly unclear, is respectfully traversed. Applicants respectfully disagree with the Examiner's assertion that there is insufficient antecedent basis for the phrase "gene(s) of interest" in claim 2 (Office

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Action, page 7). Contrary to the Examiner's assertion, it is respectfully submitted that the claim is clear as written.

However, consistent with the telephone discussion with the Examiner, and in order to reduce the issues and advance prosecution, this rejection has been rendered moot by the amendments submitted herewith. As currently amended, claim 9 recites "said first gene of interest." Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, the present application is respectfully submitted to be in condition for allowance. Accordingly, reconsideration and favorable action with respect to the pending claims is respectfully requested. In the event any issues remain to be resolved in view of this communication, the Examiner is invited to contact the undersigned at the number given below so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date 4/8/05

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